

# PSJ3

# Exhibit 476

# Drug Abuse/Diversion

# Media Coverage of Rx Abuse Raises Access Concerns, Lack of Transparency

## KUOW.ORG

Prescription Supply

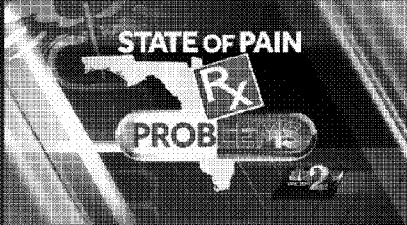
**'Opiate Refugees' Caught Between Pharmacies, Suppliers And The Law**

BY PATRICIA MURPHY

## THE WALL STREET JOURNAL.

**This Is No Way to Fight Drug Abuse**  
HDMA President and CEO John M. Gray

March 8, 2013



## CLICK ORLANDO

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**New report shows DEA contributed to prescription drug shortage**

DEA response to increase limits on controlled substances not timely, report states

Author: Erika Washington, Consumer Reporter, Fill-in anchor, [ewashington@wkmg.com](mailto:ewashington@wkmg.com)  
Published On: Mar 25 2015 11:15:00 PM EDT Updated On: Mar 26 2015 12:01:57 AM EDT



## Pharmalot

**DEA Contributes to Shortages of Drugs With Controlled Substances: Report**

By ED SILVERMAN

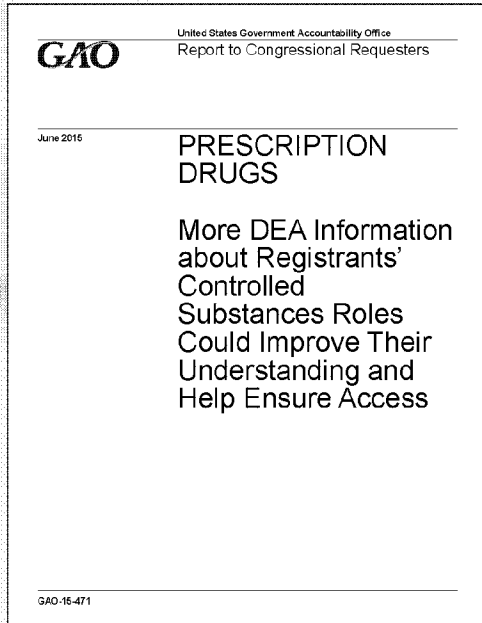
## Orlando Sentinel

Opinion

This article is related to: Drugs and Medicines, insurance

**DEA should not interfere with physicians, pain patients**

# GAO Report Highlights DEA's Shortcomings



DEA “should solicit input from distributors, or associations representing distributors, and develop additional guidance for distributors regarding their roles and responsibilities for suspicious orders monitoring and reporting.”

## GAO's Key Recommendations

- Identify and implement means of cost-effective, regular communication with the supply chain;
- Solicit input from distributors, or associations representing distributors, and develop additional guidance for suspicious orders monitoring and reporting; and,
- Solicit input from pharmacists, or associations representing pharmacies and pharmacists, about appropriate guidance for pharmacists.

# House Passes DEA Bill; Senate Next Up




**dsn.** DRUG STORE NEWS

HDMA in testimony to Congress: Government, industry should partner on combating Rx drug abuse

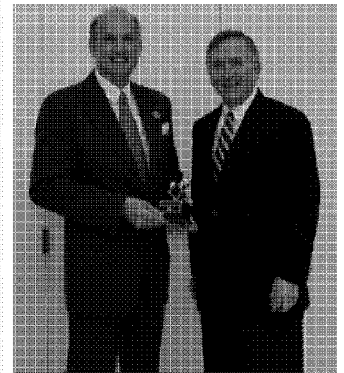
APRIL 8, 2014

## Reps. Marino, Blackburn Hail Passage of Prescription Drug Enforcement Legislation

Apr 21, 2015 | Issues: Health

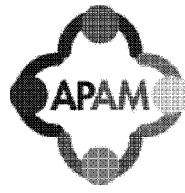
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Reps. Marino, Blackburn Hail Passage of Prescription Drug Enforcement Legislation



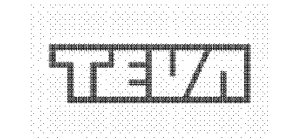
# Hatch/Whitehouse Bill - S. 483

- Legislation defines “imminent danger,” establishes a correction action process and requires a report to Congress
- H.R. 471 passed the House – April 21, 2015
- S. 483 – referred to Judiciary Committee



**Alliance to Prevent the  
Abuse of Medicines**

The mission of the Alliance is to raise awareness of the issue of prescription drug abuse and craft achievable solutions while serving as a resource for policymakers and the media.



# National Medicine Abuse Awareness Month – October 2015



- HDMA partnership with CADCA, CHPA and Gannett.
- Encourages parents, community coalitions to educate and talk about substance abuse.

## Recent History

In December 2013 HDMA hosts a Drug Diversion/DEA Strategy Task Force meeting to develop recommendations and potential strategies to address Rx abuse & diversion (See Tab 3)

Developed recommendations in the following areas:

- Work with other supply chain stakeholders to provide achievable solutions
- Address specific challenges with DEA
- Initiate public relations branding campaign

# 2013 Guiding Principles

- Work to **ensure** healthcare providers receive the medically necessary medicines to treat their patients and improve public health
- **Coordinate** with wide range of supply chain partners and regulatory agencies to help prevent diversion of Rx drugs
- Work to **educate** suppliers, customers and policymakers about industry efforts to help prevent Rx Abuse and diversion

## Recent Discussion at PPC

- What is the role of distributors in the Rx Abuse epidemic and how can we engage more effectively?
  - Is the goal to provide assistance? To customers or consumers?
  - To educate? And, who are we educating?
  - To protect the industry's interests and prevent undue regulatory impact and reputational harm?
  - To be good corporate citizens?

# Caveat for Recommendations

- Strategy should be **National** in scope
  - Federal Regulatory and Exec Branch
  - Congressional
  - State Legislative, Regulatory & Exec Branch
- Position HDMA/Industry proactively
- Assess programs/policies that could be implemented (directly/indirectly) to reduce diversion and abuse

## PPC Recommendations

- Develop materials that members can utilize to explain their obligations and responsibilities under the CSA to their customer base
- Develop materials (or refresh existing materials) to position HDMA more proactively on what the industry is doing to prevent diversion and abuse
- Direct attention to the primary causes of diversion and abuse – even if these are outside the industry's control

# Disposal

# Supreme Court and Alameda County



## Pharmaceutical Industry Must Pay for Drug Take-Back Programs

- Take-back ordinance upheld on May 19.
- HDMA working to ensure distributors not included.

### FOR PUBLICATION

#### UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA;  
GENERIC PHARMACEUTICAL  
ASSOCIATION; BIOTECHNOLOGY  
INDUSTRY ORGANIZATION,  
*Plaintiffs-Appellants,*

v.

COUNTY OF ALAMEDA; ALAMEDA  
COUNTY DEPARTMENT OF  
ENVIRONMENTAL HEALTH,  
*Defendants-Appellees.*

No. 13-16833

D.C. No.  
3:12-cv-06203-  
RS

OPINION

Appeal from the United States District Court  
for the Northern District of California  
Richard Seeborg, District Judge, Presiding

Argued and Submitted  
July 11, 2014—San Francisco, California

Filed September 30, 2014

Before: N. Randy Smith and Morgan Christen, Circuit  
Judges, and Lawrence L. Piersol, Senior District Judge.\*

Opinion by Judge N.R. Smith

\* The Honorable Lawrence L. Piersol, Senior District Judge for the U.S.  
District Court for the District of South Dakota, sitting by designation.

# EPA Proposed Pharmaceutical Waste Rule – Released Aug. 31

Official publication “in a few weeks”; 60-days to comment

## Good News:

- EPA partially backed off nonsaleable returns by proposing that “Non-creditable” = “waste”, *e.g.*, if returned 1+ years after expiration.
- Covers healthcare facilities & reverse distributors but “*definition of ‘healthcare facility’ does not apply to ... wholesale distribution ...*” (as long as they don’t meet EPA’s definition of reverse distribution).

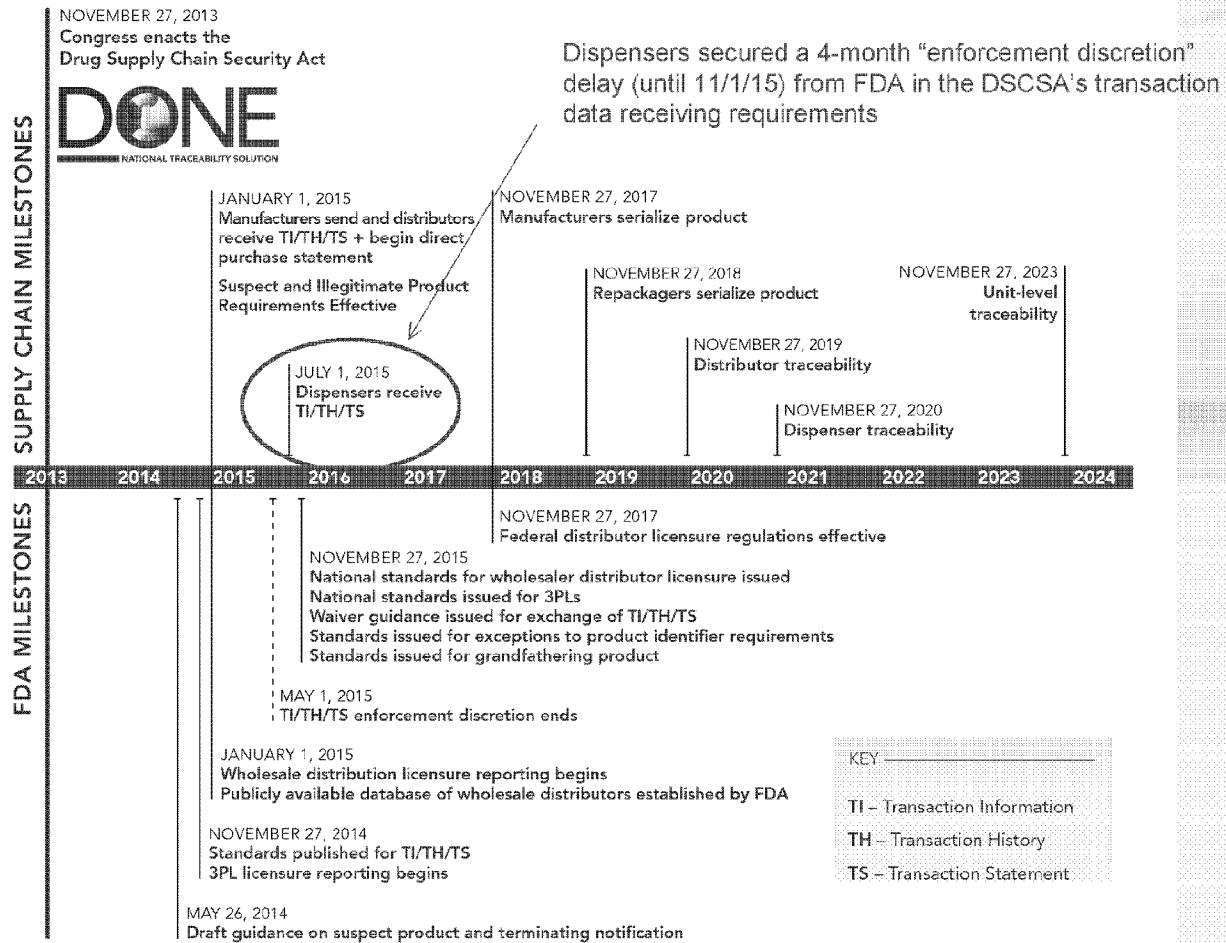
## Bad News:

- Very broad *e.g.*, includes supplements as “pharmaceuticals”; potential large impact on WD customers
- States may establish more stringent requirements**
- Forward distributors likely included in reverse distributor definition**

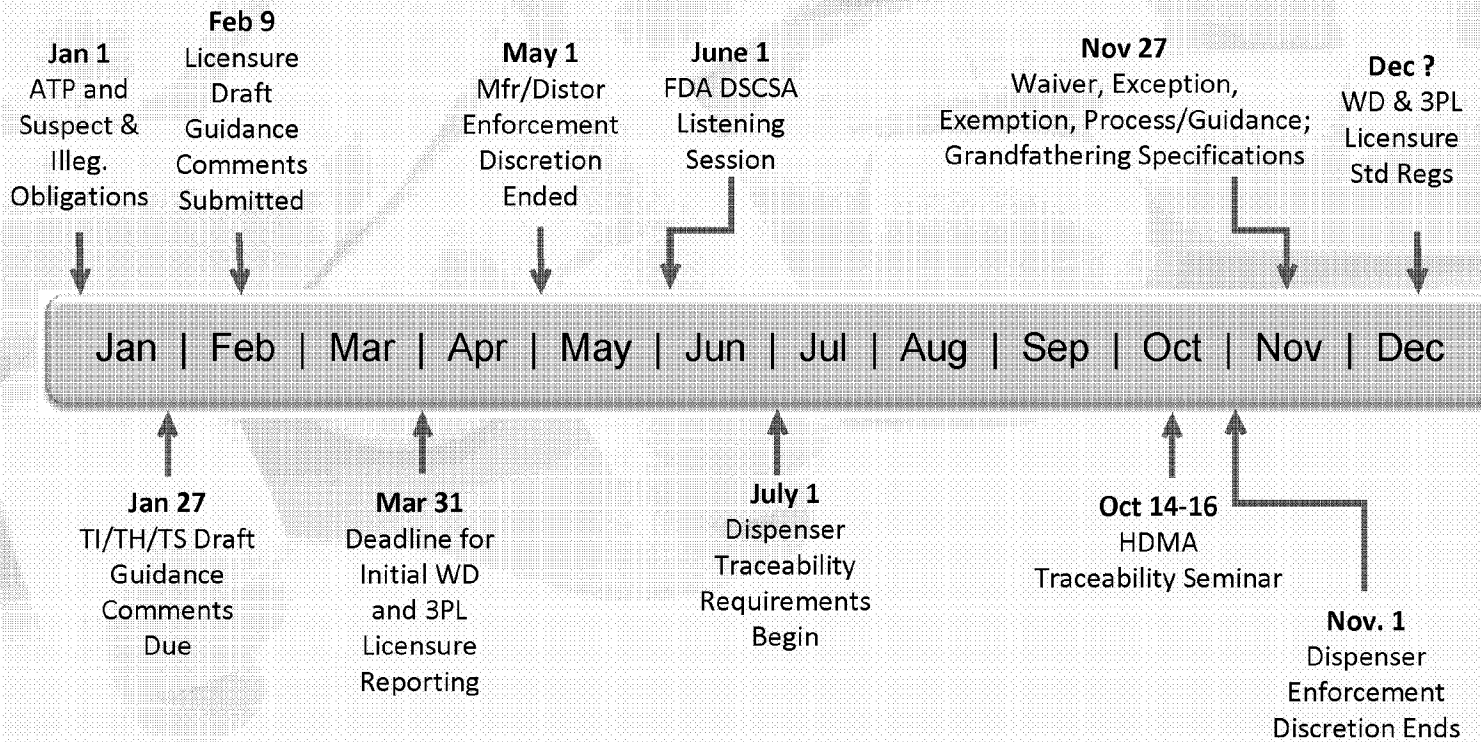
# Still Analyzing, but Examples of Potential Additional Concerns

- Large and complex; definitions inconsistent with FD&C Act
- Even if forward distributors don't meet reverse distributor definition, reverse distributor requirements may inadvertently impact forward distributors' returns practices, costs
- Analyzing for possible implications for DEA's final disposal rule
- Will it incentivize dispensers to send more returns to WD's (that should have gone to rev. distributors)?
- Much more
- Note: HDMA is forming a Work Group to help develop public comments

# Traceability



# Key DSCSA 2015 Milestones



# Continuing FDA Interactions

- 2015 to date - provided multiple written communications to FDA:
  - TI/TH/TS draft guidance
  - state licensure reporting
  - state licensure of 3PLs
  - suggestions for anticipated guidance on Waivers, Exceptions and Exemptions
  - 340B
- FDA “Listening Session” (June 1)
- Note: FDA planning a 2023 pilot

# Implementation/Support Activities Continue

- Distributors continue on-boarding customers - transaction data receiving/storage
- HDMA outreach/education, *e.g.*, multiple member, dispenser and others' questions; 5 Webinars; Traceability Seminar
- Begun 2019 returns requirements preparations; includes a Pilot of possible compliance mechanisms
- 2023 Pilot(s) in coordination with FDA, PDSA, Rx 360, et al.
- See timeline for FDA guidances, regs, etc.
- Extensive State outreach

# Tax Policy

# Federal Tax Reform & LIFO Repeal

HDMA continues to work with the NAW LIFO Coalition to oppose repeal of the LIFO tax accounting standard

- Actively briefing members of Congress/staff about the punitive impact of repeal on HDMA distributor members.
- Nearly all primary pharmaceutical distributors affected by a repeal would need to borrow funds to pay a retroactive tax on LIFO reserves.
- Based on current income tax rates, a retroactive tax on LIFO reserves would represent an average of 132 percent of annual pre-tax income. Smaller distributors would be the hardest hit by the retroactive tax as a percentage of their annual pre-tax income (183 percent).

# State Tax initiatives

## 2015 Overview

- **Ohio** – Governor John Kasich (R) advocated for an increase the state's commercial activity tax (CAT) to underwrite a reduction in the personal income tax. No action on CAT this year expected. Tax Policy Study Commission is next step (Sept/Oct 2015)
- **Nevada** – Governor Brian Sandoval (R) introduced and passed a gross receipts tax (0.101% above \$4M receipts threshold) to close a projected budget deficit and underwrite a significant education initiative. Tax implemented July 1, 2015.
- **Connecticut** – Legislation to require manufacturers and wholesalers to collect a sales tax (6.35%) on the sale of all Schedule II controlled substances to fund drug abuse prevention and treatment programs. Failed to pass before June 3 adjournment.

# State Tax initiatives

## 2016 Forecast

- **Oregon** – A coalition of the state public employee unions (Our Oregon) have filed a series of ballot measures that call for tax increases on large employers and individuals in top income tax brackets (2.5% tax, plus \$30,001, in excess of \$25M receipts)
- **Michigan** – A ballot committee (Citizens for Fair Taxes), predominantly constructed of labor unions, aims to put in place a ballot that will call for a near doubling of the state's corp income tax from 6 to 11 percent.
- **Projected Budget Shortfalls** – the following states have already acknowledged a strong likelihood to encourage tax reform to address significant budget shortfalls: AZ, MA, CT, FL, CA, MD, WA, PA, LA and IL.

# State Tax Policy Consultant

In order to enhance HDMA's coverage of state tax issues, and to replace the resource we had in prior years, plans are under way to add a State Tax Policy Consultant for the remainder of this year (and 2016). Services will include:

- Regular updates on broader state tax developments;
- Timely alerts regarding activity on critical issues (as defined by HDMA) as they develop;
- More in depth analysis and information about the status of, or prospects for, any state legislative or regulatory proposal;
- Quarterly calls with HDMA and its members to discuss trends in the state tax policy world and respond to questions from HDMA staff and members.

# Reimbursement

# AMP Rule Imminent

The Office of Management and Budget (OMB) is currently reviewing the AMP Final Rule. Expected release by end of October, but....

HDMA Actions to date:

- Met with CMS Center for Medicaid and CHIP Services (John Coster) on December 4, 2014, to review previously submitted comments outlining industry concerns with proposed rule.
- Followed up in July with a letter restating our original comments and offering to be of assistance should CMS have questions.
- Working with AMP Coalition to secure a meeting with OMB prior to final release.

# Key HDMA Concerns

- Definition of Bona Fide Service Fees (BFSFs) needs revision and clarification and BFSFs must be excluded from 5i AMP to protect wholesalers' fee-based business model
- Switch to presumed exclusion is impractical and unnecessary and could impose undue burdens on wholesalers
- Government sales and BFSF must be excluded from 5i AMP to ensure adequate pharmacy and physician reimbursement
- Safeguards are needed to ensure that Average Acquisition Costs (AACs), Federal Upper Limit (FUL) caps and professional dispensing fees consistently provide for adequate reimbursement over time
- Changes must be made to dampen AMP and FUL volatility and to ensure that FULs are not inappropriately applied in product shortage situations

# ASP – Federal Issues

- Prompt pay – H.R. 696/S. 506
  - Removes prompt pay discount from calculation of ASP
- Sequester relief – H.R. 1416
  - Prevent application of sequestration to ASP reimbursement for Part B drugs during FY 2016 and 2017

# Drug Costs Under Scrutiny

Drug prices coming under increasing scrutiny by payers and legislative bodies:

- Ongoing Congressional investigation into generic drug pricing
- New Kaiser Foundation survey indicating growing concern about drug prices
- State ballot measures calling for more transparency in drug pricing as well as access to preferred pricing programs

# 340B Program Changes

On August 27, the Health Resources and Services Administration (HRSA) released a “guidance” to provide greater clarity into topics pertaining to:

- Definition of Covered Entities
- Definition of Eligible Patient
- Criteria for Contract Pharmacies
- Registration, recertification, termination criteria
- Clarity of the GPO prohibition and exceptions
- Audit Criteria (CEs/Mfrs, Mfrs/Ces)